SONOMED INC.

E-Z Scan™ 5500+ Series

AB5500+ Combined A-Scan / B-Scan

B5500+ B-Scan

Operators Manual

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CE 0413

5550-A-1901-1C

Unit Serial Number: _____

Software Version: _____

Caution: In the United States, federal law restricts this device to use by or on the order of a physician.

Version 1 / Revision C

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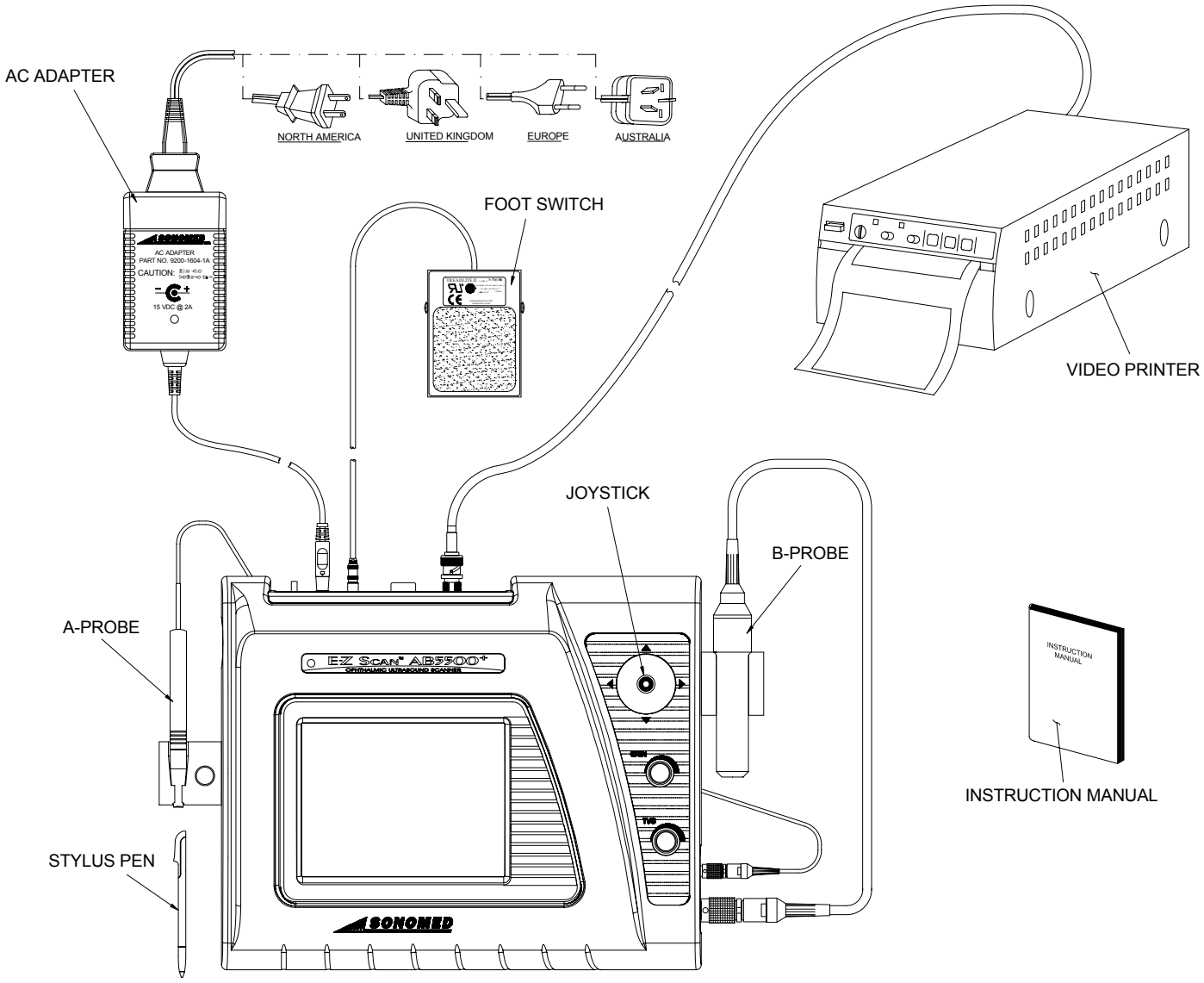


E-Z SCAN 5500+

SONOMED INC.

Section 1
INTRODUCTION

1.1 SYSTEM DESCRIPTION

The E-Z SCAN™ series is the latest generation ophthalmic ultrasound diagnostic imaging instrument manufactured by industry leading Sonomed. The series consists of the following models:

- **E-Z SCAN™ B5500+.** This B-scan system allows for easy two-dimensional B-scan imaging of the eye and orbit.
- **E-Z SCAN™ AB5500+.** This A/B-scan system combines full function A-scan Biometry capability with the above mentioned B-scan imaging module.

The system utilizes a high-resolution backlit liquid crystal display (LCD) with a "touch screen" interface by which the user can enter information and view the ultrasound image and other data. The system is compact and lightweight thereby making it extremely portable, and the adjustable legs can be tilted to several angles for user comfort and ease of viewing.

This manual is intended to provide a thorough overview of the E-Z SCAN™ series of instruments and their capabilities. Every effort has been made to make these instruments easy to understand and use. Nevertheless, it is strongly recommended that the operator read the entire operation manual (as well as any manuals supplied with the system) before operating the instrument. If after reading the manual, or at any other time, a question concerning the operation of the instrument should arise, please feel free to contact Sonomed customer service at 1-800-227-1285 (or in NY at 516-354-0900) at any time with questions or concerns regarding system use.

Thank you for your trust in Sonomed to provide for your ophthalmic imaging needs.

1.2 B-SCAN FEATURES

As mentioned, the B-Scan mode of the E-Z SCAN™ series allows for imaging the internal structures of the eye and the surrounding tissue in the presence of opaque media or cataracts.

By placing the B-probe against a patient eye using a suitable ultrasound transmission gel, a live B-Scan ultrasound image of the eye can be obtained. The image can then be "frozen" and the measurements or reviewer annotation will be displayed along with other pertinent information.

After completion of scanning, a hardcopy may be obtained of the results using the optional black & white video printer.

Several features help to distinguish the Sonomed E-Z SCAN™ 5500+ series including:

- High Resolution, Flat Screen Color Display with Touch Screen
- Softkey Menu Driven Operation
- Three (3) Different Imaging Modes
  - B-Scan Only
  - B-Scan with A-Scan Vector (B/a)
  - A-Scan with Reference B (A/b)
- Selectable A-Scan Vector in Simultaneous Display Modes
- Gain and TVG (Time Variable Gain) Controls
- Selectable Post-Processing Enhancements (Grayscale and Color)
- Selectable Compression Curves (Log, Linear, and S-curve)
- Zoom and Pan Controls
- Area and Distance Measurements

- Image Annotation from Dictionary
- Small, Lightweight B-scan Probe
- External Monitor/Video Printer Output
- Five (5) Customizable User Profiles
- Self-Test Routines at Start-Up

See Appendix A for full specifications of the E-Z SCAN™ 5500+.

1.3 A-SCAN FEATURES *(for AB5500+ Model Only)*

The A-Scan mode of the EZ-SCAN™ AB5500+ allows for measuring of the axial length (AXL) of an eye and calculating the associated IOL power for an implanted lens.

By placing the A-probe against a patient eye, and aligning the probe along the visual axis, a live A-Scan ultrasound pattern for an AXL measurement can be obtained. The image can then be "frozen" and the measured value for the AXL will be displayed along with other pertinent information. Using the AXL, Keratometer readings, and an IOL program parameter (depending on the specific program selected), the system calculates the required IOL power.

After completion of measurements and calculations, a hardcopy may be obtained of the results using the video printer included with the system. The hardcopy will include all information that is displayed on the screen when the print key is depressed.

Several features help to distinguish the Sonomed E-Z Scan 5500+ series, including:

- Live A-Scan Display
- Gain Control
- Storage of Five (5) Scans for Later Review and IOL Calculation
- Five (5) Different Examination Modes
  - Cataract
  - Dense Cataract
  - Aphakic
  - Pseudophakic (with five (5) IOL types: PMMA, Acrylic, Silicone-I, Silicone-II, or Custom.)
  - Manual
- Velocity Compensation for Pseudophakic Lens Type (PMMA, Acrylic, Silicone-I & II and "Custom" lenses).
- A-Scan Measurement Review Capability
  - Axial Length, Anterior Chamber Depth, and Lens Thickness for Each Scan.
  - Axial Length Average and Standard Deviation for Up to 5 Scans.
- A-Scan Measurement Review Mode
- Six (6) Available IOL Formulas
  - Binkhorst
  - Regression-II
  - Theoretic-T
  - Holladay
  - Hoffer-Q
  - Haigis (optional)
- Immersion Capabilities
- Five (5) Customizable User Profiles
- Clinical Accuracy ±0.1 mm
- User-Performed Calibration Check
- Self-Test Routines at Start-Up
- Standard or Soft-Touch Probe Styles Available

1.4 ACCESSORIES & OPTIONS

Standard accessories supplied with the E-Z SCAN™ 5500+ system are:

- B-Scan Probe*
- A-Scan Probe *(for AB5500+ Model)
- External AC Power Supply with Cord*
- Instruction Manual
- Touch Screen Stylus
- Black & White Video Printer
- Ultrasonic Coupling Gel

** Use only those items supplied with the instrument or approved by Sonomed, Inc. Use of unapproved parts may damage the instrument or degrade performance.*

Options available with the E-Z SCAN™ 5500+ include:

- Carry Case

For additional supplies, please contact Sonomed Customer Service via telephone at 800-227-1285 / 516-354-0900, or via fax at 516-354-5902.

Section 2
GETTING STARTED

2.1 UNPACKING

The E-Z SCAN™ 5500+ system is carefully packed to prevent damage during shipment. Before unpacking, please note any visible damage to the outside of the shipping containers.

Each item should be checked in order to ensure that all ordered items have been received. The following table lists the standard items which should be received with each particular system (note: additional optional items may also have been ordered).

	System	
Item	B5500+	AB5500+
E-Z SCAN™ Unit	•	•
Touch Stylus	•	•
Foot Pedal	•	•
AC Adapter	•	•
Instruction Manual	•	•
B-Scan Probe	•	•
A-scan Probe		•
Coupling Gel	•	•
Printer & Paper	•	•
Calibration Cylinder		•
Carrying Case	Optional	

Each item should be examined for any noticeable defects or damage that may have occurred during shipment. If any defect or damage exists, please call your local representative or Sonomed immediately to report the problem.

2.2 SAFETY CONSIDERATIONS

FOR YOUR PROTECTION, please read these safety instructions completely before installing, applying power to, or operating the system.

BEFORE OPERATION, the instrument and this manual should be reviewed for safety markings and instructions. Specific warnings and cautions are found throughout the manual where they apply. These must be followed to ensure safe operation and to maintain the instrument in a safe condition.

REVIEW any other manuals and instruments supplied with the system in the same manner.

KEEP this manual for future reference.

TERMS AS MARKED ON THE EQUIPMENT

CAUTION indicates a personal injury hazard not immediately accessible as one reads the markings, or a hazard to property, including the equipment itself.

WARNING indicates conditions or practices that could result in personal injury or loss of life.

DANGER indicates a personal injury hazard immediately accessible as one reads the marking.

TERMS AS USED IN THIS MANUAL

CAUTION statements identify conditions or practices that could result in damage to the equipment or other property.

WARNING statements identify conditions or practices that could result in personal injury or loss of life.

GENERAL WARNINGS!

Use only the AC Adapter that is supplied with the system. (P/N: 9200-1604-XX)

To avoid explosion, DO NOT operate this product in the presence of flammable gases or fumes.

To avoid personal injury, DO NOT remove the product covers or panels.

No user serviceable parts inside. DO NOT attempt to service the system except as described in the operating instructions. For all other servicing refer to qualified service personnel.

Disconnect AC Power before cleaning the case.

Turning on a cold instrument near 0° C, will permanently damage the instrument.

Never autoclave a transducer or expose it to high heat.

The transducers are fragile. Dropping or striking any probe can cause it to malfunction. Handle all probes with care. If a probe is dropped, inspect it carefully for chips before using.

GENERAL CAUTIONS!

DO NOT cover instrument with a dust cover when power is being applied to the instrument.

Guard against any small objects or liquid from entering the instrument.

The system should be placed on a level, stable surface during operation. A system and cart combination should be moved with care. Quick stops or uneven surfaces may cause the cart to overturn.

Only connect or disconnect the probe while the instrument is in the OFF position.

2.2 SOMMAIRE DES MESURES DE SÉCURITÉ

POUR VOTRE PROTECTION, S.V.P. lire ces instructions de sécurité complétement avant d'installer et de mettre sous tension ou d'opérer le system.

AVANT L'UTILISATION, l'instrument et ce manuel devraient être revue pour prendre connaissance des instructions et des points de sécurité. Des avertissements spécifiques et précautions se retrouvent à diverses endroits où elles s'appliquent elles doivent être suivient pour assurer une opération et le maintien sécuritaire de l'instrument.

ATTENTION dans certain cas d'autres manuels pourraient être fournis avec cet appareil et devraient être revus de la même manière.

GARDER ce manuel pour référence future.

TERMES TEL QU'INSCRIT SUR L'EQUIPMENT

ATTENTION - Risque potentiel de blessure ou dommage à la propriété ou à l'équipment même.

AVERTISSEMENT- Risque de blessure ou de perte de vie.

DANGER - Indique un risque immédiat de blessure.

TERMES TEL QU'UTILISER DANS CE MANUEL

ATTENTION - Risque de dommage à l'équipement ou à d'aurtes propriétés.

AVERTISSEMENT - Risque de blessure ou de perte de vie.

AVERTISSEMENTS GÉNÉRAUX

Utilisez seulement l'adaptateur à C.A. qui est fourni avec le `système.`

Afin d'éviter tout risque d'explosion ne pas utiliser ce produit en présence de produits inflammable. L'opération d'un produit électrique dans de tel conditions constitue un risque d'explosion.

Pour éviter tout risque de blessure ne pas retirer le couvert ou le panneau.

NE PAS utiliser le produit sans couvert et panneau bien en place.

NE PAS tenter de réparer le system sauf tel que décrit dans le manuel autrement référez vous à du personnel compétant.

MISE EN GARDE

NE PAS obstruer les trous de ventilation situés à l'arriere et dessous l'instrument et ne jamais recouvrir l'instrument durant l'operation.

Protéger contre tous petits objets ou liquides pouvant pénétrer l'instrument.

Débrancher l'instrument si il ne sera pas utiliser pour une longue période.

Le system doit être placé de niveau sur une surface stable durant l'opération. Le system et chariot doivent être déplaces avec soins. Les arrêts rapides, forces excessives, et surfaces inégales peuvent endommager le system.

2.3 SYSTEM SET-UP

CONNECTING ACCESSORIES

1. Place the E-Z SCAN™ on a flat level surface.

2. Connect the foot pedal cable connector to the rear panel of the system into jack labeled "FOOT PEDAL". Place the foot pedal on the floor.

3. Verify that the Power Switch located on the rear panel of the system is in the "OFF" position.

4. Connect the jack plug of the AC adapter cable to the DC input jack located on the rear panel of the system.

5. Connect the AC adapter to a proper AC power source (i.e. wall outlet). The AC adapter is a universal voltage model which can run from 100 VAC to 240 VAC 50/60 Hz power source.

⚠ CAUTION

This instrument may be damaged if operated with an AC adapter other than that provided.

⚠ IMPORTANT

It is recommended that an uninterruptible power supply be utilized to regulate line voltage coming into the system.

6. Plug the connector of the B-Scan probe into the jack on the right side of the system labeled "B PROBE". Before inserting the probe, be sure to line up the red indicator marks on both the jack and cable connector.

7. If the system is an AB5500+, plug the connector of the A-scan probe into the jack on the right side of the system labeled "A PROBE". Before inserting the probe, be sure to line up the red indicator marks on both the jack and cable connector.

PRINTER SET-UP

1. Place the printer on a flat level surface.

2. Connect one end of the BNC cable to the "VIDEO IN" connector on the printer's rear panel and the other end to the matching connector on the rear side of the system labeled "VIDEO OUT".

3. See the included printer instruction manual for paper loading and power up instructions.

POWER UP CHECK

1. Slide the Power Switch located on the rear panel to the "ON" position.

2. Verify that the green LED on the face of the system illuminates and that the Main Screen appears on the display (see Figure 2-1).

Figure 2-1 Main Screen Display

⚠ WARNING

In the event of loss of stored data including the system calibration values and user settings due to a discharged battery, a "STORED DATA LOST" warning message will be displayed. Please contact Sonomed service department for further assistance.

3. If either LED does not illuminate or Main Screen does not appear, immediately power OFF the system and contact your local representative or Sonomed for assistance.

USING THE TOUCH SCREEN

The touch screen provided with the *E-Z SCAN*™ system is a highly sensitive device which enables selections to be made and recorded on screen. On-screen selections should only be made by gently using a finger or the provided Stylus pen (do not use a pencil, pen, or other sharp object).

⚠ CAUTION

Care should be taken when using or storing the system so that excessive force is not applied to the touch screen, as it is may become permanently damaged.

SCREEN BRIGHTNESS ADJUSTMENT

1. From the Main Screen, select the **[B-SCAN]** mode key (see Figure 2-1).

2. Press the **[MENU]** key located in the top right corner of the display. A drop down menu will appear.

3. Press the **[BRIGHT]** key and use the **[+]** and **[-]** keys which appear, to adjust brightness up or down respectively. *The drop down menu will disappear in approx. 10 secs.*

SLEEP MODE

The E-Z Scan is equipped with a "sleep mode", which increases the life of touch screen display. If the system is idle for 15 minutes while powered on, the screen display will shut off. The system can be "awaken" by simply touching the display.

SETTING THE DATE AND TIME

1. From the Main Screen, select the **[SET DATE]** key at the bottom of the screen (see Figure 2-1). Verify that the Enter Date and Time Screen appear on the display (see Figure 2-2).

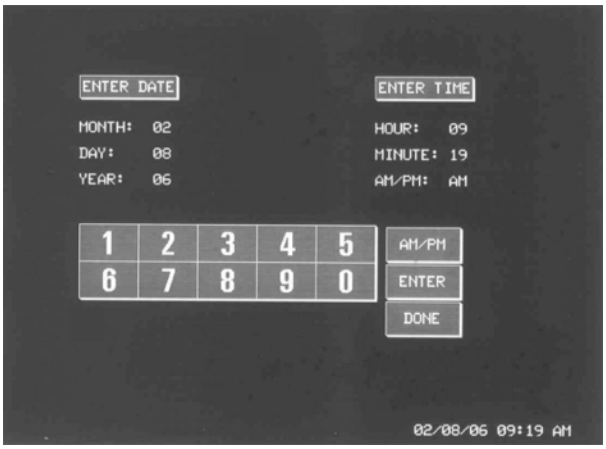


Figure 2-2 Set Date and Time Screen Display

2. To edit date, select the **[ENTER DATE]** button. Enter the appropriate two digits for the month (for example, "01" for January), and then select the **[ENTER]** button. Repeat for the day and year.

3. To edit the time, select the **[ENTER TIME]** key. Enter the appropriate two digits for the hour, and then select the **[ENTER]** button. Repeat for entering minutes. Hit the **[AM/PM]** button to select the correct setting and then the **[ENTER]** button.

4. Press **[DONE]** to return to the Main Screen.

5. Verify that the correct Date and Time are now displayed in the bottom right corner of the display.

Section 3
A-SCAN OPERATION AND CLINICAL USE
(For E-Z Scan AB5500+ Model Only)

The A-Scan mode of the EZ-SCAN™ AB5500+ allows for measuring of the axial length (AXL) of an eye and calculating the associated IOL power for an implanted lens.

By placing the A-probe against a patient eye, and aligning the probe along the visual axis, a live A-Scan ultrasound pattern for an AXL measurement can be obtained. The image can then be "frozen" and the measured value for the AXL will be displayed along with other pertinent information. Using the AXL, Keratometer readings, and an IOL program parameter (depending on the specific program selected), the system calculates the required IOL power.

After completion of measurements and calculations, a hardcopy may be obtained of the results using the video printer included with the system. The hardcopy will include all information that is displayed on the screen when the print key is depressed.

3.1 SELECTING A-SCAN MODE

1. Touch the **[A-SCAN]** key on the Main Screen (see Figure 3-1).

Figure 3-1 Main Screen Display

2. Ensure the Calibration Screen appears.

3.2 CALIBRATION

It is recommended that the functionality of the A-scan portion of the EZ-SCAN™ be verified by means of the calibration procedure prior to performing actual measurements.

The EZ-SCAN™ defaults into the Calibration Screen when the A-Scan mode is selected.

To perform the calibration procedure, follow these steps:

1. Place a small amount of ultrasound transmission gel onto the calibration cylinder which is located on the A-probe holder assembly.

2. Place the probe onto the calibration cylinder. The probe should be placed perpendicular to the cylinder. Press the footswitch or the [FREEZE] key.

3. Observe the measurement displayed in the upper left corner of the display. The measurement will freeze once it has captured a satisfactory pattern and measurement.

4. Verify that the measurement obtained is 10.00 ±0.1 mm.

Note: If necessary, the gain control may be adjusted by turning the "Gain" knob located to the right of the display. The resulting gain level in "dB" (decibels) will be displayed.

> ⚠ **IMPORTANT**
>
> *If a measure within 10.00 ± 0.1 mm cannot be obtained, contact Sonomed service department for assistance.*

It is recommended that calibration be performed prior to obtaining measurements; however, the calibration mode may be skipped if so desired by touching any of the other menu buttons (ex: MEASURE) on the right side of the screen after the Calibration Screen appears.

3.3 SYSTEM SET-UP

ENTERING USER INFORMATION

Up to five (5) different user profiles may be entered and permanently stored within the EZ-SCAN™ memory. User profiles allow for user identification and selection of the preferred IOL formula and Lens constants.

1. ***Entering / Editing User Identification***. Touch the **[USER]** key. Verify that the User Data Screen appears (see Figure 3-2).

Figure 3-2 User Data Display

Touch the **[USER1]** key then either the **[ADD USER]** to add a new user profile, or the **[EDIT]** button to edit an existing user profile. Enter the name of the user by touching the appropriate alphanumeric buttons. When finished, touch the **[ENTER]** button.

Touch the **[USER#]** key to advance to the next user selection.

Touch the **[DONE]** key when finished.

2. ***IOL Formula Selection***. Within the User Data Screen, touch the **[FORMULA]** button to scroll through the different available IOL formulas. Note that default values for the associated constants are given with each formula. The constant default values are shown in Table 3-1.

IOL constants (main and alternate) are entered two per user for each of five users for a total of 10 constants.

Table 3-1
IOL Formula Constant Default Values

IOL Formula	Constants	Default Values
Hoffer-Q	ACD	3.68 mm
Theoretic-T	A-Constant	115.8 D
Regression-II	A-Constant	115.8 D
Holladay	S-Factor	-0.02 mm
Binkhorst	ACD	3.68 mm
Haigis (option)	A-Constant	115.8 D

In order to change the associated constants, touch the **[CONSTANTS]** key. Verify the Constants Screen appears (see Figure 3-3).

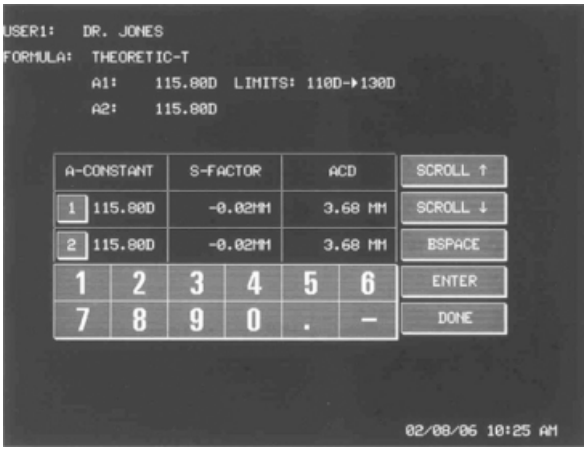


Figure 3-3 Constants Screen Display

As shown, all of the constants are displayed in the table on the Constants Screen. Select the **[1]** or **[2]** keys to edit the appropriate constant. Enter the desired constant and then press **[ENTER].** Touch the **[DONE]** key when finished.

ENTERING PATIENT INFORMATION

Patient information including name, identification number, K readings, and eye to be examined can be stored within the EZ-SCAN™ memory. Only one patient may be stored at a time, but the information will remain until overwritten.

1. Touch the **[PATIENT]** key. Verify that the Patient Screen appears (see Figure 3-4).

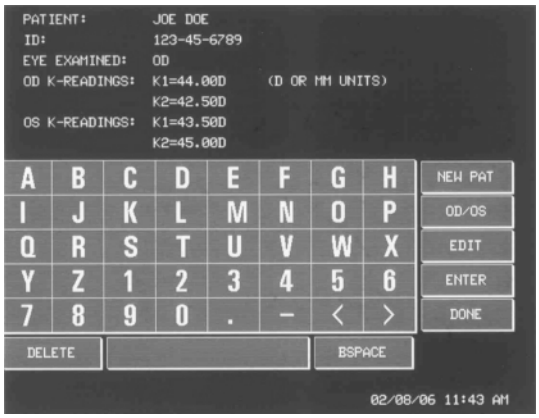


Figure 3-4 Patient Screen Display

2. Within the Patient Screen, enter information for a new patient by touching the **[NEW PAT]** key or edit the existing patient information by touching the **[EDIT]** key.

3. Enter the patient name by touching the appropriate alphanumeric keys. When finished entering the name, touch the **[ENTER]** key.

4. Enter the patient ID number, and touch the **[ENTER]** key when finished.

5. Enter the eye to be examined by touching the **[OD / OS]** button to toggle between right and left. When the correct eye has been selected, touch the **[ENTER]** button.

6. Enter the K1 and K2 readings touching **[ENTER]** after each reading. The K1 and K2 readings may be entered in either Diopters (range of 20.00D to 60.00D) or as radius of curvature (range 5.63mm to 16.87mm). Touch the **[DONE]** button when finished entering the patient information.

> **⚠ WARNING**
>
> *The EZ-Scan assumes a keratometer index of refraction of 1.3375 for converting K readings. If entering K readings in millimeters which were obtained using a keratometer with a different index, the values must first be manually converted to Diopters and then entered.*

3.4 PATIENT PREPARATION

Apply a drop of topical anesthetic to the eye that is to be measured prior to performing the A-scan.

DIRECT CONTACT MEASUREMENTS

The patient should be seated in a comfortable, upright position preferably in an examination chair with a headrest. If the scan is to be performed using the "hand-held" method, the headrest should be positioned comfortably behind the patient's head in order to minimize movement away from the probe.

If an applanating device is to be used, bring the patient's forehead into contact with the cross bar and rest the chin on the chin support. Adjust the chin support so that the patient's eyes are approximately 1" to 2" below the cross bar.

NOTE: Applying excessive force to the probe will cause discomfort to the patient and distort the eye, resulting in incorrect measurements.

IMMERSION TECHNIQUE

The patient should be seated with their head tilted slightly back. An ordinary chair is usually all that is needed, although in certain difficult cases, both patient and user will benefit from the use of a regular examination chair with headrest. Place a towel on the patient's shoulder. Consult the instructions supplied with the particular immersion shell for further directions regarding the proper use of the shell.

3.5 PATIENT EXAMINATION

Following entry of user and patient information, A-scan measurements may be obtained. Select the **[MEASURE]** button from any screen to display the Measure Screen (see Figure 3-5).

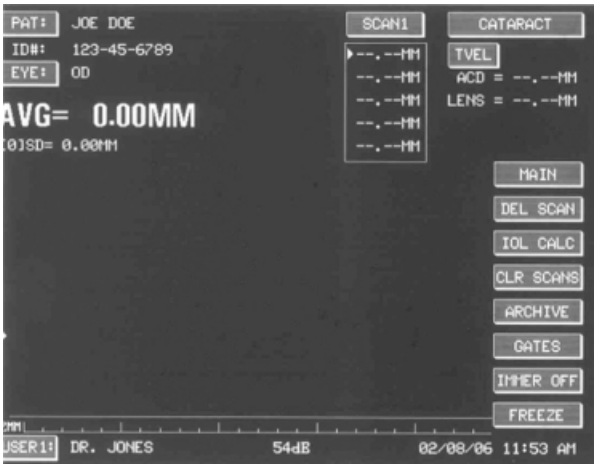


Figure 3-5 Measure Screen Display

DIRECT CONTACT SCANNING IN AUTOMATIC MODE

The EZ-SCAN™ is able to recognize an acceptable A-scan pattern and automatically capture the image, depending upon the type of measurement to be made.

1. ***Examination Mode***. Ensure the correct examination mode is selected as indicated by the mode button in the upper right corner of the Measure Screen. The examination mode may be changed by repeatedly touching the mode key until the desired mode is shown. The following automatic capture modes are available:

   - Cataract
   - Dense Cataract
   - Aphakic
   - Pseudophakic
   - Manual Mode

When Pseudophakic mode is selected, one of five different pseudophakic lens types (PMMA, Acrylic, Silicone-I, Silicone-II or a User "Custom" Lens) may be selected touching the **[LENS]** key. The average tissue velocity will be automatically adjusted for the selected lens type. The velocity for the "Custom" lens can obtained from the manufacturer and entered by the user.

2. ***Tissue Velocity***. In Auto Mode, the EZ-SCAN™ will select the correct number of gates to use as well as the appropriate velocities. Insure that the appropriate tissue velocities are selected by pressing the **[TVEL]** key once a particular Eye Type is selected. The user has the option of changing the velocity for any area by pressing the appropriate key (TVEL1, TVEL2, etc.) In Pseudophakic Mode, the user can also select a "Custom" lens by pressing the **[TVEL]** key and then selecting **[CUSTOM LENS]**. (See Figure 3-6). Press **[ADD LENS]** and type the Lens Name followed by **[ENTER]**. Type the axial correction (if known) followed by [**ENTER**] (if not known, simply press [**ENTER**]; then type the correct velocity followed by [**ENTER**].

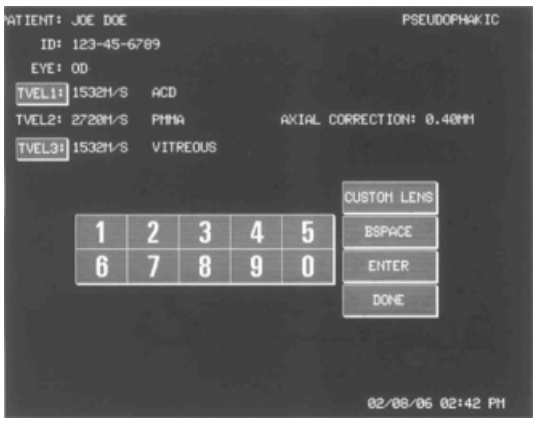


Figure 3-6 Custom Lens Selection

In Manual Mode, the user can select the number of gates (2, 3 or 4) by pressing the [**#GATES**] key, as well as selecting the appropriate velocities for each area. (See figure 3-7).

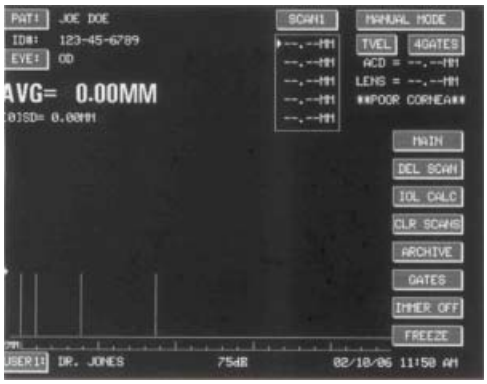


Figure 3-7 Manual Mode Screen Display

Touch the **[TVEL#]** key to edit the tissue velocity for a particular gate area, enter the appropriate value, and then touch the **[ENTER]** key. Verify that the tissue velocity has changed, then press **[DONE]**.

3. ***Immersion Option***. Ensure that the immersion option is OFF as displayed on the **[IMMER**] selection key. The immersion option may be toggled "ON" and "OFF" by touching the **[IMMER/(ON/OFF)]** key.

4. ***Scan Eye***. Instruct the patient to look towards the red fixation light in the probe tip and visually align the probe along the patient's visual axis. Move the probe forward until contact with the cornea is achieved. Once contact is made, a live A-scan pattern will be displayed and no further forward movement should be made.

5. ***Automatic Scan Capture***. If the scan meets all the parameters of the selected examination mode, it will immediately be frozen, saved and a long audible tone will be emitted signifying that the instrument has accepted the measurement.

   If necessary, the gain control may be adjusted by rotating the **Gain Control** knob located on the panel to the right side of the instrument. The gain (in dB) is displayed on the bottom center of the display. The default gain is 40; however a gain of 65 to 75 has been shown to give satisfactory results for most eyes. The gain setting may not be changed for any scan which has already been frozen.

   Once accepted, the scan pattern will be displayed on the screen; the axial length will be calculated and stored under "**SCAN 1**" in the upper center of the Measure Screen. The location of the key structures in the scan waveform will be indicated by flashing gate markers displayed above the waveform as well as a blinking red dot at the threshold level of each echo. The anterior chamber depth and lens thickness will also be displayed (except for Pseudophakic eye, where a default lens thickness is used, or for an Aphakic eye).

> ⚠ **IMPORTANT**
>
> *It is important to remember that the auto modes are meant to facilitate the examination procedure but not replace the examiner's clinical judgment. All scans should be thoroughly evaluated by the user prior to being accepted and used for calculating lens powers.*

6. ***Repeat***. The protocol can be repeated to obtain up to five (5) scans. As the scans are captured, the axial length for each is displayed in the upper center of the Measure Screen. Additionally, the axial length average and standard deviation for the group of scans will be displayed. Each scan pattern may be reviewed by touching the **[SCAN#]** button to scroll through the captured scans.

Deleting Scans. If a scan is captured which is no longer desired, it may be deleted by scrolling to the scan (as described above) and touching the **[DEL SCAN]** button. Deleting a scan will remove the scan pattern and all associated data from system memory, and will exclude the associated axial length from the average and standard deviation calculations. If **all** scans are no longer desired, they may all be deleted by touching the **[CLR SCANS]** button.

NOTE: *In the event that an echo is erroneously selected by the auto mode, the user can reposition the gate to the correct echo by first pressing the [GATE] key repeatedly until the desired gate marker is flashing. Once selected, the gate can be repositioned using the joystick located to the right of the display.*

MANUAL MODE

The user can select Manual Mode by continuously pressing the [**MODE**] key until "Manual" is displayed. This mode allows the user to identify and accept an echo pattern based on their clinical judgment and not use the pattern recognition software within the instrument.

When using the Manual Mode, the user can position the gates after freezing the image, by pressing the [**GATES**] key repeatedly until the desired gate is flashing and then positioning that gate using the joystick on the right side of the instrument.

The user is also able to select the number of gates required depending on the eye type. This can be accomplished once manual mode is selected by pressing the [**#GATES**] key located just below the mode key in the upper right corner of the display until the desired number of gates is displayed.

IMMERSION TECHNIQUE

In addition to direct contact measurements, a water immersion technique may be used with the EZ-SCAN™ in order to completely eliminate concerns over corneal compression skewing results. The technique requires the use of an immersion scleral shell as described below using the automatic capture examination mode.

1. ***Examination Mode***. Ensure the correct examination mode is selected as indicated in the upper right corner of the Measure Screen. The examination mode may be changed by touching the mode button until the desired mode is shown. The following examination modes are available:

    - Cataract
    - Dense Cataract
    - Aphakic
    - Pseudophakic
    - Manual Mode

3. ***Tissue Velocity***. Ensure the appropriate tissue velocities are selected by pressing the **[TVEL]** key once the examination MODE has been selected.

Table 3-2
Default Tissue Velocities

Structure	Velocities
ACD	1532 m/s
Natural Lens	1641 m/s
Vitreous	1532 m/s
PMMA Lens (Pseudophakic)	2720 m/s
Acrylic Lens (Pseudophakic)	2120 m/s
Silicone-I Lens (Pseudophakic)	980 m/s
Silicone-II Lens (Pseudophakic)	1090 m/s

The tissue velocity may be changed by first touching the **[TVEL]** button to display the Tissue Velocity Screen (see Figure 3-6).

Touch the **[TVEL#]** button to edit the desired tissue velocity, enter the appropriate number, and touch the **[ENTER]** button. Verify that the tissue velocity has changed before returning to the Measure Screen by pressing **[DONE]**.

In Pseudophakic Mode, the user can also select a "Custom" lens by pressing the **[TVEL]** key and then selecting **[CUSTOM LENS]**. Press **[ADD LENS]** and type the Lens Name followed by **[ENTER]**. Type the axial correction (if known) followed by [**ENTER**] (if not known, simply press [**ENTER**]; then type the correct velocity followed by [**ENTER**].

3. ***Immersion Option***. Ensure that the immersion option is ON as indicated on the **[IMMER]** selection key. The immersion option may be toggled between ON and OFF by touching the **[IMMER]** key. A small white "GATE" will appear on the left side of the baseline. *If the probe is aligned in the shell correctly, the corneal echo should appear in the center of this gate.*

4. ***Prepare Immersion Shell (see instructions provided with shell)***. Unscrew the probe handle and pull it away from the probe tip. Insert the probe tip into the shell, advancing the probe until its tip is parallel with the line scored in the shell barrel. Once the correct position has been obtained, ensure that the probe is secure.

> ⚠ **IMPORTANT**
>
> *Proper measurement data will only be obtained if the probe is properly placed in the Immersion shell. Proper positioning must be confirmed by examining the captured scan waveform.*

   Once the probe has been positioned within the shell, attach a tubing set to the shell. Consult the instructions supplied with the particular Shell for proper use. Fill a 5cc or 10cc syringe with saline or BSS and connect to the tubing set.

5. ***Applying the Immersion Scleral Shell***. Rest the syringe on the towel which has been placed on the patient's shoulder, and hold onto the shell with probe in preparation for insertion. Direct the patient to look downward, toward the floor. Lift the patient's upper eyelid and insert the flared rim underneath the lid (the upper portion of the shell should make contact with the sclera while the lower part should be held away from the eye). Then direct the patient to look straight ahead toward the red fixation light in the probe tip. Pull the patient's lower eyelid down and *gently pivot* the lower portion of the shell into the lower fornix (i.e. *NOT* sitting atop a fold in the conjuctiva). This pivotal motion avoids contact with the cornea and ensures centering of the device around the limbus.

6. ***Scan Eye***. Press the footswitch and pick up the syringe from its place on the patient's shoulder. Slowly inject the saline or BSS into the shell. As soon as the liquid fills the shell sufficiently to reach the tip of the probe (about 2cc), the characteristic waveforms of immersion biometry will be visible on the display. Gently tap the side of the probe tip to insure that no air bubbles have been trapped on the tip of the probe.

7. ***Automatic Image Capture***. If the scan meets all the parameters of the selected examination mode, it will immediately be frozen, saved and a long audible tone will be emitted signifying that the instrument has accepted the measurement. The proper location of the corneal echo should be confirmed on the scan waveform (see Figure 3-8). The first spike seen on the waveform is the probe "main bang" followed by the corneal echo. The acceptable position for the corneal echo is indicated by the corneal echo window (horizontal bar) displayed below the waveform. The echo from the cornea must fall within this window for a proper immersion scan. If the corneal echo is outside of this window, the position of the probe within the Scleral Shell should be adjusted accordingly.

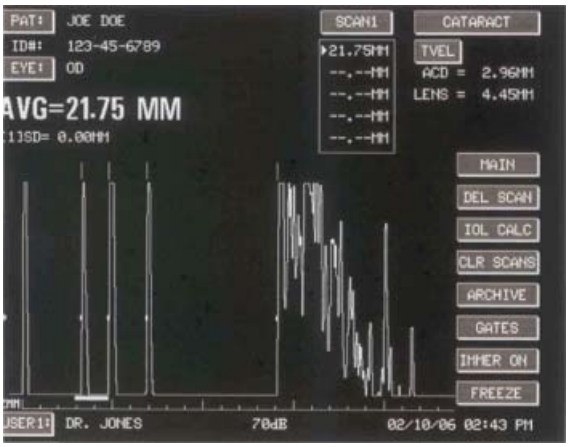


Figure 3-8 Immersion Mode Record Print

If necessary, the gain control may be adjusted by rotating the **[GAIN]** knob located to the right of the Measure Screen. The resulting gain setting will be displayed in the bottom center of the display. Frequently a lower gain setting may be used in Immersion scanning than typically used in Direct Contact mode.

Once accepted, the scan pattern will be displayed on the screen; the axial length will be calculated and stored under "SCAN 1" in the upper center of the Measure Screen. The anterior chamber depth and lens thickness will also be displayed. Gate markers will be

displayed above the waveform to indicate the detected positions of the *cornea*, *anterior lens, posterior lens* and the *retina.*

> ⚠ **IMPORTANT**
>
> *It is important to remember that the auto modes are meant to facilitate the examination procedure but not replace the examiner's clinical judgment. All scans should be thoroughly evaluated by the user prior to being accepted and used for calculating lens powers.*

8. ***Repeat***. The protocol can be repeated to obtain up to five (5) scans. As the scans are captured, the axial length for each is displayed in the upper center of the Measure Screen. Additionally, the axial length average and standard deviation for the group of scans will be displayed. Each scan pattern may be reviewed by touching the **[SCAN#]** button to scroll through the captured scans. The Scleral Shell should be left in place until all desired scans are achieved.

9. ***Deleting Scans***. If a scan is captured which is no longer desired, it may be deleted by touching the **[DEL SCAN]** key as described earlier. Deleting a scan will remove the scan pattern and all associated data from system memory, and will exclude the associated axial length from the average and standard deviation calculations. If **all** scans are no longer desired, they may all be deleted by touching the **[CLR SCANS]** button.

10. ***Removing the Immersion Shell***. Once all desired scans have been captured, raise the upper eyelid to release the top portion of the shell from under the eyelid. Pivot the shell downward, directing the patient to continue to look straight ahead. Pull the shell away from the eye without making contact with the cornea. Upon initial release, the remaining liquid contents of the shell will spill down the patient's cheek (which can be subsequently wiped with towel or tissue).

11. ***Scanning the Fellow Eye.*** Press the [**EYE**] key to change to the fellow eye and repeat the above procedure.

PERFORMING IOL CALCULATIONS

The EZ-SCAN™ uses the measurement data and selected IOL calculation formula to determine and display appropriate IOL powers.

1. ***IOL Calculation***. After obtaining acceptable A-scans, the IOL powers can be determined by touching the **[IOL CALC]** button. The IOL Calculation Screen will be displayed (see Figure 3-9).

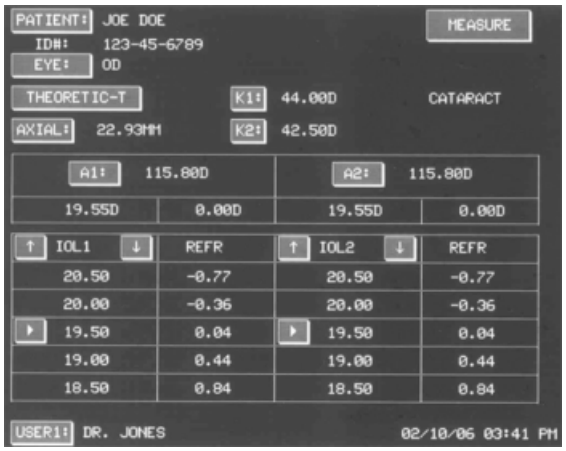


Figure 3-9 IOL Calculation Screen Display

2. ***IOL Power Table***. A table is presented which consists of commercially available IOL powers in ½ Diopter increments, and the expected refraction associated with each IOL power. At the top of each column, the exact "target" value with the associated exact IOL power is displayed. Values are given for main lens and alternative lens. The table values are calculated using the specified IOL formula (which can be changed by touching the formula button), the associated formula constants, the k-readings previously entered, and the average axial length measured.

3. ***Viewing Other IOL Powers***. The IOL power table is centered around those IOL powers which produce refraction which is as close as possible to emmetropia. Other powers and associated refractions can be viewed by scrolling using the **[↑]** and **[↓]** buttons, or by touching the **[▸]** button and entering a refraction value.

PRINTING

Printed records are available when using the video printer included with the system. Records can be obtained for each scan performed and for the IOL power calculation table.

1. ***Print Screen Format***. The video printer will print images exactly as they appear on the display. See Figures 3-10 and 3-11.

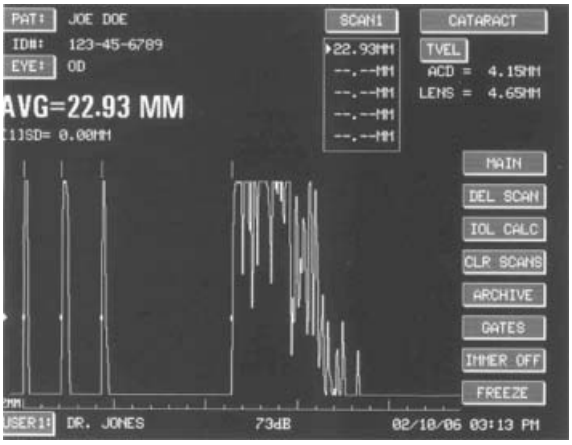


Figure 3-10 Measurement Display Record

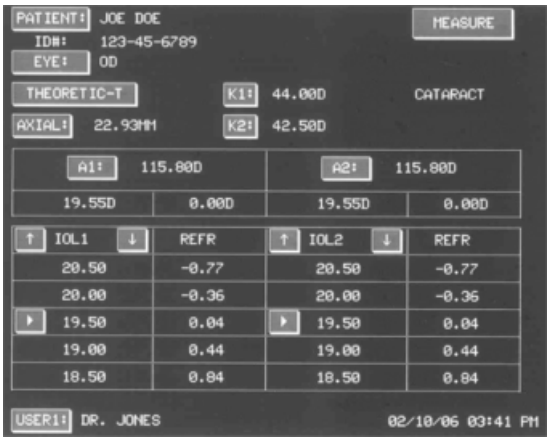


Figure 3-11 IOL Screen Record

2. ***Printing***. Touch the **[PRINT]** button on the video printer while either the Measure Screen or IOL Calculations Screen is displayed. Be sure to first press the "EYE" key to display the selected eye for printing.

3.6 IMAGE ARCHIVE

The EZ-SCAN™ includes an Archiving Feature which allows the user to download actual scans and associated scan information to a computer. Use of this feature requires a serial cable (not supplied) which should be connected at one end to the RS-232 serial type connector on the rear of the unit and the other end to a serial port on the computer. A software program for downloading and viewing these images is also required and is available from Sonomed. Information regarding this software can be obtained by contacting the Sonomed Customer Service Department at 800-227-1285.

To archive while in the A-scan Mode, press the [**ARCHIVE**] key while in the Measure Mode.

To archive while in the in B-scan Mode, press the [**MODE**] key. This will cause a pull down menu to appear. Select the [**ARCHIVE**] key to initiate the information transfer.

The transfer of data should only take a short time. A message will be displayed informing the user of the progress. Once completed, the user can store the information on a computer or other digital media.

NOTE*: Patient information will need to be entered in order to use the Archiving Feature.*

3.7 SOURCES OF ERRORS AND HOW TO AVOID THEM

There are a few common errors which may occur when performing A-scans which deserve some mention. These errors are described below.

CORNEAL COMPRESSION

One of the most common mistakes made when performing axial length measurements is applying excessive pressure on the eye with the probe. When using a Direct Contact Probe (and to a lesser extent the Soft-Touch Probe) it is possible to indent the cornea to the extent that the measurements will be adversely affected.

In using the Direct Contact Probe extreme care should be taken to insure that only enough force necessary to maintain contact with the cornea is used. The problem is minimized to some degree in the case of the Soft-Touch probe since excessive pressure is evidenced by the fact that the probe will begin to recede into its housing.

Checking the measured ACD values listed in the Measure Scan screen for any inconsistencies will generally indicate whether or not there is sufficient corneal compression to require deleting that particular scan from the group.

A-SCAN PATTERN

Recognizing an optimal echo pattern is the basis for performing accurate A-scan measurements. Even when using one of the automatic modes the user should review each scan to determine whether or not the scan pattern is acceptable. It is important to remember that the automatic modes are meant to facilitate the examination procedure but not replace the examiner's clinical judgment. The examination results should not be blindly accepted and by reviewing the scans the user will reduce the possibility of any errors which may cause less than optimal results. In reviewing, the user should compare the similarity of the characteristics of the particular scan under consideration with those of an optimal A-Scan pattern.

Characteristics of an Optimal A-Scan are as follows:

1. The cornea, lens and retinal echoes should all be approximately the same height.

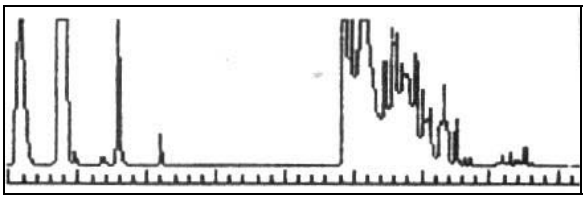


Figure 3-12 Correct A-Scan Pattern

2. The retinal echo should rise sharply from the baseline forming a 90º angle.

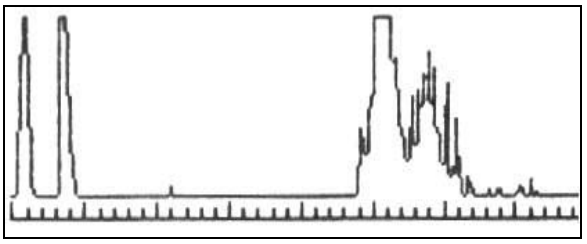


Figure 3-13 Poor Retinal Rise

3. The orbital pattern beyond the Retina should present a gradual decline. A sharp drop in this pattern may indicate that the probe is not aligned along the visual axis.

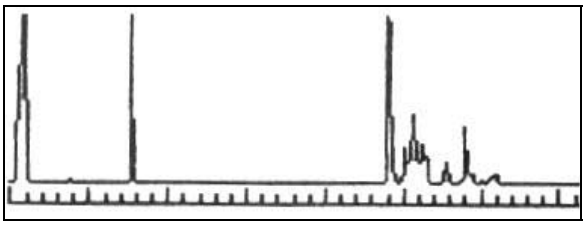


Figure 3-14 Poor Retinal Decline

The user should always strive to achieve these three basic criteria before accepting any measurements as accurate. Some anatomical variations may prevent all such criteria from being simultaneously achieved in any given scan. In such a case, a scan may have to be accepted based on its meeting the remaining criteria.

EXAMINATION MODES

Before performing an axial length measurement the user should always verify the operating mode (cataract, dense cataract, aphakic, pseudophakic or manual mode). Since this mode governs the manner in which the instrument evaluates an A-Scan pattern and the parameters the instrument will utilize in its calculations, mistakes and/or large numerical errors will be avoided (even though the A-scan pattern appears satisfactory).

IMMERSION TECHNIQUE

Although use of the water immersion technique completely eliminates corneal compression as a complicating factor, and can greatly assist with the alignment of the probe along the visual axis, it is still necessary to review and analyze waveforms to ensure an acceptable reading.

The probe must be properly positioned within the Immersion shell in order for the EZ-Scan™ to automatically capture the waveform. If a seemingly proper waveform is not automatically captured, check to see whether the leading edge of the corneal echo is either inside (as shown in Figure 3-15) or outside the limits of the corneal window. In either instance a warning message "POOR CORNEA" will be displayed.

Only scans with a steeply rising retinal spike should be accepted. A minor "stair-stepping" is inherent in a digital waveform, but a reading which is registered on a third or higher step should not be accepted. In other words, the horizontal threshold line (which is the "reading" line) should cross on the first or second vertical step of the retinal spike. Additionally, the retinal spike should be "stepped" only by the thickness of a single line – scans with additional lines should be rejected.

There should also be a strong scleral spike, immediately posterior to the retinal spike. The scleral spike amplitude should be close to that of the retinal spike, but can be slightly lower or higher.

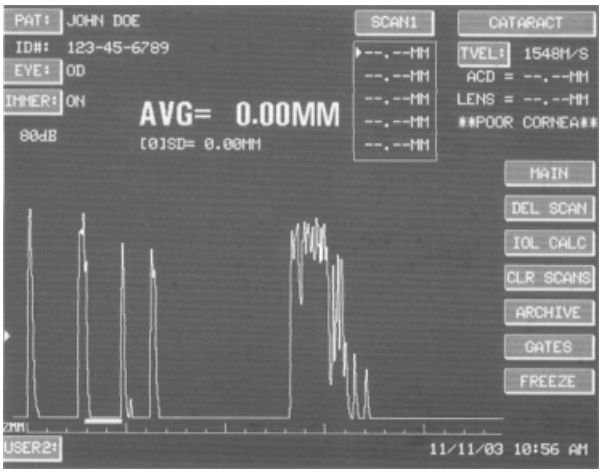


Figure 3-15 Poor Position in Immersion Mode (Corneal Echo "left" of the Gate)

Section 4
B-SCAN OPERATION AND CLINICAL USE

The B-Scan mode of the E-Z SCAN™ 5500+ allows for imaging of the eye and surrounding tissue. After completion of scanning, a hardcopy may be obtained using the video printer supplied with the system.

4.1 SELECTING B-SCAN MODE

1. Touch the **[B-SCAN]** key on the Main Screen (see Figure 4-1).

Figure 4-1 Main Screen Display

2. Ensure the B-Scan Screen appears (see Figure 4-2).

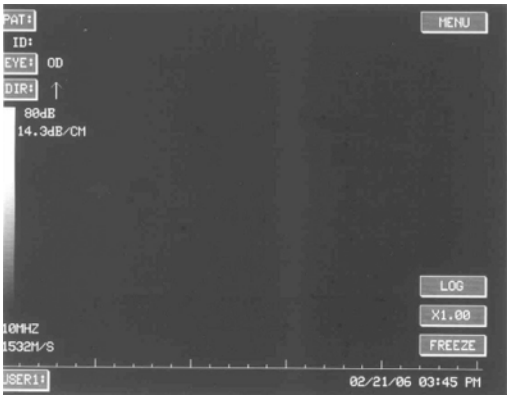


Figure 4-2 B-Scan Screen Display

4.2 SYSTEM SET-UP

ENTERING USER INFORMATION

Up to five (5) different user profiles may be entered and permanently stored within the E-Z SCAN™ memory. User profiles allow for user identification and selection of a particular system operating parameters (e.g. Gain, TVG, Processing).

1. ***Entering / Editing User Identification***. Touch the **[USER]** button. Verify that the User Data Screen appears (see Figure 4-3).

Figure 4-3 User Screen Display

Touch the **[ADD USER]** key to add a new user profile, or the **[EDIT]** button to edit an existing user profile. Enter the name and/or ID of the user by touching the appropriate alphanumeric keys. When finished, touch the **[ENTER]** key.

Touch the **[SAVE SETTINGS]** button to save the system operating parameters (Gain, TVG, Processing) for the current user.

Touch the **[USER#]** key to advance to the next user selection.

Touch the **[DONE]** key when finished.

ENTERING PATIENT INFORMATION

Patient information including name, identification number and eye to be examined can be stored within E-Z SCAN™ memory. Only one patient may be stored at a time, and the information will remain until overwritten.

1. Touch the **[PAT:]** key. Verify that the Patient Screen appears (see Figure 4-4).

Figure 4-4 Patient Screen Display

2. Within the Patient Screen, enter information for a new patient by touching the **[NEW PAT]** key or edit the existing patient information by touching the **[EDIT]** key.

3. Enter the patient name by touching the appropriate alphanumeric keys. When finished entering the name, touch the **[ENTER]** key.

4. Enter the patient ID number, and touch the **[ENTER]** key when finished.

5. Enter the eye to be examined by touching the **[OD / OS]** key to toggle between the left and right. When the correct eye has been selected, touch the **[ENTER]** key. Press **[DONE]** to return to the examination screen.

4.3 PATIENT PREPARATION

The patient should be seated in a comfortable, upright position preferably in an examination chair with a headrest. The headrest should be positioned comfortably behind the patient's head in order to minimize movement away from the probe.

Apply a small amount of transmission gel to the tip of the B-scan probe.

4.4 PATIENT EXAMINATION

Following entry of user and patient information, a B-scan image may be obtained. Touch the **[FREEZE]** key to start/stop scanning or depress and release the footswitch to toggle the scanner between "live" and "freeze".

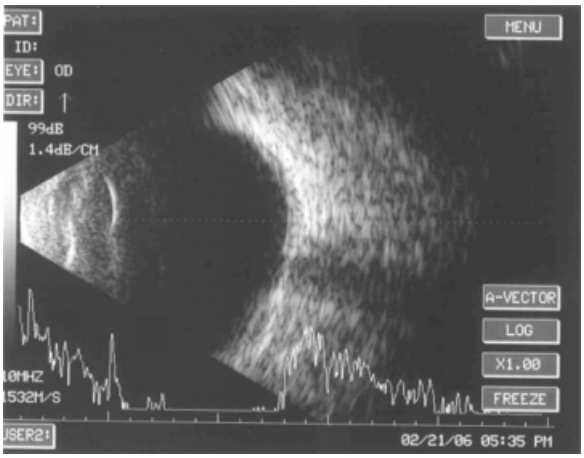


Figure 4-5 B-Scan Screen Display

It may be necessary to apply additional transmission gel to the probe periodically during the exam to insure proper coupling of the probe tip to the eye. The operating controls (softkey buttons and menus) are described in more detail in the following section.

4.5 B-SCAN OPERATING CONTROLS

The operation of B-scan mode is controlled with the following soft key buttons and menus. On-screen directions appear, where needed, for when each soft-key is pressed.

Table 4-1
Soft Key Functions

KEY	FUNCTION
PATIENT	Switch to Patient screen for Patient information entry.
EYE	Change selection of eye examined (OD / OS)
DIR	Directional marker for probe orientation.
USER	Switch to User Data screen
MENU	Turn menu display on/off
PROCESS	Select processing function (LOG / LIN / S-CURVE)
ZOOM	Adjust image zoom factor (0.5 to 2.0 magnification)
FREEZE	Start/stop scanning
A-VECTOR	Adjust position of A-cursor (only in B/a or A/b modes)

Table 4-2
Menu Functions

MENU	FUNCTION
MODE	Select scanning mode: B-only, B/a or A/b
MEASURE	Display Measurement menu: Distance or Area measurements
ENHANCE	Display image Enhance menu.
REJECT	Adjust which signal levels to view or reject.
COLOR MAP	Select grayscale or colorized display maps
RESOLUTION	High resolution of 256 lines (50mm. scan depth) -or- Low resolution or 128 lines (60mm. scan depth)
BRIGHT	Adjust brightness of display backlight.
ANNOTATE	Display list of words & phrases to annotate the image
ARCHIVE	Transfer the current image and settings to a computer for storage
MAIN	Return to Main starting screen

PRINTING

Printing of any screen is performed by pressing the Print button on the video printer. The image which appears on the display at the time the print button is pressed will be printed exactly as it appears on the display. The user should read the instruction manual which is included with the particular video printer supplied with the system.

SOFT-KEY DESCRIPTION

MENU

Pressing the [**MENU**] key will cause a drop down menu to appear on the display. This menu will automatically erase in 10 seconds if no key is selected.

MODE

Pressing the [**MODE**] key will enable the user to select the display mode:

B
B-scan only displayed

B/a
B-scan with small A-scan vector displayed

A/b
Large A-scan with reduced B-scan

MEASURE

Pressing **[MEASURE]** will enable the user to select either the "Distance" or "Area" feature as well as adjust the "velocity" setting.

When **[DISTANCE]** is selected, a blinking cursor will appear on the display. Using the joystick, the user can position the cursor where the desired measurement is to begin and then press [**SET**]. A second blinking cursor will then appear and the distance between the two cursors will be shown at the top of the display. Using the joystick, the user can reposition the second cursor to the end point of the desired measurement. Pressing [**SET**] will lock the measurement. Pressing [**NEXT DIST**] will enable the user to perform a second measurement while keeping all the previous measurement information on the display. [**CLEAR**] will erase one measurement function at a time.

Pressing **[AREA]** will cause a blinking cursor to appear on the display. Using the joystick, the user can position the cursor at a point where the measurement is to begin. Pressing [**SET**] will enable the joystick to trace an outline around an object. Once the outline is complete, pressing [**SET**] again will enable the Area measurement to be shown at the top of the display. Pressing [**BACKUP**] will allow the user to erase previous measurement points along the trace. Pressing [**CLEAR**] will erase all measurement data.

Pressing **[VELOCITY]** will allow the user to adjust the sound velocity prior to making a distance or area measurement depending on the media through which the measurement will be made. When this key is pressed, a patient information screen will appear. Pressing the [**TVEL**] key will cause the current velocity setting to be replaced with a blinking cursor. Using the displayed keypad, the user can enter the desired velocity, followed by [**ENTER**]. This will then return the user to the examination screen.

ENHANCE

This function will allow the user to select features which will enhance the image and make it more "readable" as described below.

Pressing **[REJECT]** will cause [+] / [-] keys to appear. Pressing these keys will either increase or decrease the level of echoes which will be displayed by making 'black" all the signals of the B-scan image which are below the selected level. The "Gray Scale Bar" on the left of the display will show which levels remain.

Pressing the **[GRAY]** key will cause the "Gray Scale Bar" to scroll through the different color schemes available. The color schemes included are listed as: Gray, Color 1, Color 2, & Color 3 and selected map will be displayed on the key once selected.

Pressing **[Hi Res/Lo Res]** will change the current resolution setting. Changing to Hi Res, will increase the resolution (256 lines) and display a scan depth of 50mm. Changing to Lo

Res. will decrease the resolution (128 lines) but increase the scan depth to 60mm.

Normal setting should be Hi Res. Unless there is a need to increase the imaging depth further into the orbit.

BRIGHT

Pressing this key will cause [+] / [-] keys to appear. Pressing these keys will enable the user to either increase (+) or decrease (-) the brightness of the display.

ANNOTATE

The annotate feature allows the user to add text and/or symbols to the stored B-scan image.

1. Press **[MENU]** and select **[ANNOTATE]** from the drop down menu.
2. Use the joystick to align the cursor at the desired location on the image.
3. Using the arrow keys, located on the top and bottom of the text box to scroll and highlight the desired text/symbol and press [**SET**]. The selected text will then appear at the selected position on the display.
4. Repeat this procedure for additional text or press [MENU] to exit.

Note: Pressing **[EDIT]** will allow the user to add additional text to the menu.

1. Use the joystick to move the cursor to the next available space.
2. Press **[ADD WORD]** and use the keypad to type the desired text.
3. Press **[ENTER]**.
4. Press **[DONE]** to return to previous screen.

ARCHIVE

Pressing this key will enable the user to download the displayed images from the EZ-scan to a Personal Computer via the RS-232 connector on the rear of the unit. Once this key is pressed a status message will be displayed.

Sonomed Scan Viewer Software is available directly from Sonomed. Information concerning this software can be obtained by contacting Sonomed's customer service department at 1-800-227-1285.

MAIN

This key will return the operator to the initial main screen where the selection of either [**B-SCAN**] or [**A-SCAN**] can be made.

EXTERNAL CONTROLS

(FRONT PANEL)

GAIN (+/-):

Permits the user to adjust the gain setting for both A-scan and B-scan examinations. The gain setting is shown on the display in the "measurement" screen (A-scan) and the "examination" screen (B-scan).

TVG (+/-):

The TVG control allows the user to adjust the "Time Variable Gain" setting while in the B-scan examination mode. Like the Gain setting above, this control can only be adjusted while in "Live" mode. Once the image is "frozen", the control is no longer active. Since the anterior segment of the eye is in close proximity to the transducer, the energy level is much higher resulting in more "noise" which may cloud the area. The TVG control enables the user to adjust the gain setting for the anterior segment of the eye, enabling a clearer view. Adjusting both the Gain and TVG controls is necessary in order to obtain the clearest and most detailed image.

JOYSTICK:

The Joystick has numerous functions within the B-scan mode. The joystick is used for "panning" the image through the display (re-centering the image when using the Zoom feature, etc,); used to move the cursors while making measurements in the Area or Distance modes; and aligning the text cursor on the display when using the "Annotate" feature.

(REAR PANEL)

VIDEO OUT:

Used to connect the EZ-scan to an external video printer, monitor or other video device.

RS-232:

Used to enable transmission between the EZ-scan system and a computer via serial cable.

FOOT SWITCH:

Used for connection of supplied foot switch to EZ-scan.

POWER:

Used to connect AC Adapter supplied with system (PN 9200-1604-1A).

ON/OFF:

Turn power to the EZ-scan on or off. Green indicator LED will light when power is supplied to the system.

4.6 IMAGE ARCHIVE

The EZ-SCAN™ includes an Archiving Feature which allows the user to download actual scans and associated scan information to a computer. Use of this feature requires a serial cable (not supplied) which should be connected at one end to the RS-232 serial type connector on the rear of the unit and the other end to a serial port on the computer. A software program for downloading and viewing these images is also required and is available from Sonomed. Information regarding this software can be obtained by contacting the Sonomed Customer Service Department at 800-227-1285.

To archive while in the in B-scan Mode, press the [**MODE**] key. This will cause a pull down menu to appear. Select the [**ARCHIVE**] key to initiate the information transfer.

To archive while in the A-scan Mode, press the [**ARCHIVE**] key while in the Measure Mode.

The transfer of data should only take a short time. A message will be displayed informing the user of the progress. Once completed, the user can store the information on a computer or other digital media.

NOTE*: Patient information will need to be entered in order to use the Archiving Feature.*

Section 5
MAINTENANCE AND SERVICE

5.1
ROUTINE MAINTENANCE

The maintenance described below should be performed routinely so that the EZ-SCAN™ is always operating in a safe and reliable manner. Calibration check and probe examination, etc. are good practices to carry out prior to using the system. For example checking the instrument calibration is necessary if reliable measurements are to be made, while a physical examination of the probe will lessen the possibility of injury to the eye. In any event, a routine consideration of all the items is a good practice and may help to avoid major problems in the future.

SYSTEM GENERAL INSPECTION

1. Be sure the instrument is located on a flat, level and stable surface and in a comfortable viewing position.

2. Examine each item for any defects or damage.

3. Visually examine the instrument, prior to use, for loose or disconnected cables or cables which appear frayed or broken.

4. For electrical-shock protection, the AC adapter should only be plugged into a properly wired AC receptacle.

5. Verify that operational conditions are such as to prevent either small objects or liquids from entering the unit in order to prevent component damage or a fire hazard.

6. Verify that the foot pedal functions properly, is placed in a convenient location, and that the cable is free from becoming entangled.

CLEANING

System: Periodic cleaning of the EZ-SCAN™ enclosure with a soft cloth is all that is usually required to keep the system looking new. Stubborn stains may be removed using a soft cloth dampened with a mild detergent solution.

> **⚠ CAUTION**
>
> *Never use strong solvents such as benzene, acetone, thinner or abrasive cleansers as these may damage the system.*

> **⚠ WARNING**
>
> *To prevent electrical shock, it is recommended that the power cord be disconnected prior to cleaning the system.*

Probes: *The Probes must be cleaned and disinfected between patients to prevent the transmission of infections. It is the user's responsibility to ensure that the relevant standards are maintained and that the products and procedures are effective and appropriate for ophthalmic applications. The following information is provided for the guidance of users, and specific products are mentioned for illustration only. Products must be used in accordance with the particular manufacturer's instructions.*

The following guidelines should be used to prevent patient-to-patient transfer of infection:

1. The probe must be cleaned between all patients to prevent patient-to-patient transfer of infection.

2. The probe may be cleaned using Cidex liquid disinfectant, usually found in hospitals. Other FDA cleared disinfectants may also be used.

3. The Probe and cable can be immersed. Do Not immerse the connector.

4. Do Not autoclave the probe or cable.

5. After cleaning, rinse the end of the probe thoroughly with clean water to remove all traces of the liquid used.

6. Follow the instructions on the label of the disinfectants.

7. The surfaces should then be dried with a lint-free cloth.

⚠ CAUTION

DO NOT soak probes in alcohol for extended periods of time, as damage can occur.

STORAGE

When not in use, it is recommended that the power cord be disconnected and the EZ-SCAN™ be covered to keep dust and debris from entering the system. While stored the EZ-SCAN™ should be protected from temperature extremes and humidity which can cause condensation within the unit. The probes should be removed from the EZ-SCAN™ and stored where they will be protected from damage.

PROBE GENERAL INSPECTION

1. The probes should be checked daily for function as well as for any visible damage.

2. Always check the cable for frayed or broken wires which may interfere with the proper functioning of the probe.

3. When connecting the probe to the instrument be sure to align the red indicator dots on both the jack and cable connector.

4. Verify that the internal fixation light of the A-probe is operating.

5. Carefully examine the probe tip for any chipping or rough edges which may injure the cornea.

6. If applicable, examine the "Soft-Touch" mechanism of the A-probe to ensure that it slides freely and with minimal force.

⚠ CAUTION

DO NOT attempt to disassemble or lubricate the slide mechanism as this may cause permanent damage to the internal components.

5.2 A-SCAN FUNCTIONALITY CHECK

It is recommended that the functionality of the A-scan mode of the EZ-SCAN™ be verified by means of the calibration procedure prior to performing actual measurements.

The EZ-SCAN™ defaults into the Calibration Screen every time the A-Scan mode is selected. To perform the calibration procedure, follow these steps:

1. Place a small amount of ultrasound coupling gel onto the tip of the A-scan probe.

2. Place the probe onto the calibration cylinder located on the right side of the system. The probe should be placed perpendicular to the cylinder.

3. Press the footswitch and observe the measurement displayed on the touch screen display. The measurement will freeze once it has stabilized and a calibration status message will be displayed.

4. Verify that the measurement obtained is 10mm. ±0.1mm. If it is not, repeat the calibration procedure until an acceptable measure is obtained.

⚠ IMPORTANT

If a measure within 10 ±0.1mm cannot be obtained, contact Sonomed service department for further help.

It is recommended that calibration be performed prior to obtaining measurements; however, the calibration mode can be skipped if so desired by touching any of the other menu buttons on the right side of the screen when the Calibration Screen appears.

A-SCAN SENSITIVITY TEST

Sonomed A-scan probes are constructed to be reliable products which may be used for several years. However, the nature of the transducers within the probes is such that degradation can occur over extended lengths of time. The sensitivity test can determine the sensitivity of an A-scan probe, and should be performed if the probe has begun exhibiting suspect performance.

1. Connect the probe connector to the side panel jack labeled "A-PROBE". Before inserting be sure to line up the red indicator dots on both the jack and cable connector.

2. Adjust the GAIN control to maximum.

3. Press **[MEASURE]** key to view the A-Scan display.

4. Place a small amount of coupling gel onto the calibration cylinder.

5. Place probe against top surface of cylinder and apply a slight pressure to ensure good contact with the cylinder.

6. There should now be displayed three (3) echoes all equally spaced and of varying height.

7. A system operating at peak sensitivity should show a third echo at least ½ the height of the second echo.

⚠ IMPORTANT

A system where the results of the sensitivity test are such that the third echo is not at least ½ the height of the second echo (or which shows no third echo at all) may be not be sensitive enough to perform accurate scans.

In general this is due to a loss of sensitivity in the Probe. If this is the case the Probe should be replaced. However, in order to confirm that it is the probe which is the cause of the problem, it is necessary for evaluation by Sonomed.

For further assistance, please contact the Sonomed Service Department at 800-227-1285.

5.3 TROUBLESHOOTING

⚠ WARNING

To avoid personal injury, do not open system – there are no internal user-serviceable parts.

1. Check all cables and connections.

2. Check troubleshooting chart (Table 5-1) and take any suggested corrective action.

Table 5-1
Troubleshooting Chart

Symptom	Corrective Action
LCD screen does not illuminate when system powered on	Ensure AC adapter connected to system and proper power source
	Ensure power switch is in the ON position
Unable to freeze A-scans in the automatic capture mode (AB5500+ only)	Verify that the appropriate capture mode has been selected (i.e. cataract, dense cataract, etc.)
	Verify Gain level is adjusted properly
No refractive data is shown in the IOL table (AB5500+ only)	Verify that all necessary IOL data have been entered (i.e. k-readings, formula constants, etc.)
Inconsistent axial length measurements obtained. (AB5500+ only)	Check anterior chamber depth measurements – if inconsistent, may reflect corneal compression occurring during applanation
Orbital pattern beyond the retina does not gradually decline (AB5500+ only)	Ensure the probe is aligned along the visual axis
No image on B-scan Display	Verify B-probe is connected properly
	Verify Footpedal is connected properly

3. If problem cannot be solved, please contact Sonomed service department for further help. Prior to contacting Sonomed, please gather as much information as possible concerning the specific problem, and have the system and probes nearby. This will greatly aid the service representative in determining the cause of the problem.

   If it is deemed necessary to return the system and/or probes to Sonomed for service, a return authorization will be issued. Please ensure that any materials returned to Sonomed are adequately packaged to avoid any damage during shipment.

ELECTROMAGNETIC INTERFERENCE

At times during normal use, the operator may experience periods of interruption caused by interference from outside sources such as electrostatic discharge, power generators or other office equipment.

Should any outside interference cause the system to "lock-up" or begin to operate in a manner inconsistent with the manufacturers instructions, simply turning the unit off for a few seconds will usually resolve the problem.

In some cases a "hard-reset" must be performed by the operator. This will cause all stored data to be replaced with the factory default settings, and should therefore only be used when absolutely necessary. For instructions on performing a system reset, the operator should contact the Sonomed service department at 800-227-1285.

5.4 WARRANTY

Sonomed, Inc. (“Sonomed”) warrants each new instrument and its accompanying accessories and optional equipment (herein after called "Equipment") to be free from defects in material and workmanship for a period of twelve (12) months from the date of delivery to the original purchaser. This warranty is not applicable to any defect which is the result of an accident, misuse, mishandling, neglect, improper installation, improper repair or improper modification by persons other than qualified Sonomed personnel. This warranty also does not apply if the equipment has not been operated and maintained in accordance with the operating and maintenance manuals, instructions or bulletins issued in respect thereof by Sonomed. It is further understood that the cost of servicing replaceable and expendable items including parts and labor made in connection with the routine maintenance services as described in such Operators Manual is not covered under this warranty and is the responsibility of the purchaser.

This warranty is strictly limited to replacement or repair of the part which is found to be defective in material or workmanship. At the option of Sonomed said part shall be replaced or repaired free of charge F.O.B. our factory by Sonomed.

Sonomed reserves the right to make changes in the design and material of Equipment without incurring any obligations to incorporate such changes in equipment already completed on the effective date of any such change or changes.

This is the only warranty of this product and is expressly in lieu of all other warranties, express or implied by law or otherwise, including any implied warranties of merchantability and of fitness for a particular purpose. Without regard to the alleged defect, Sonomed does not, under any circumstances, assume any responsibility for the loss of time, inconvenience or other consequential damages, including but not limited to, loss or damage to personal property, or loss of revenue. Sonomed has neither assumed nor authorized any other person (including any distributor authorized to sell its equipment) to assume for it any other liability in connection with the sale of equipment.

5.5 DISPOSAL

Following use, any ultrasonic coupling gel should be wiped from the probe, treated as potentially biohazardous waste, and disposed of accordingly. Following end of useful life, any equipment including the system, probes, and power supply should be disposed of per applicable local, state, and/or federal ordinances.

⚠ WARNING

To avoid personal injury, do not open system – there are no internal user-serviceable parts.

Please contact the Sonomed Service Department for replacement of all internal components.

Section 6
SPECIFICATIONS

PHYSICAL		
Dimensions:		
Width	239 mm	9.4”
Depth	225 mm	8.9”
Height	71 mm	2.8”
Weight	2.4 kg	5.25 lbs

ELECTRICAL		
Power Consumption	10.0 W (Typical)	
Incoming Line Voltage (±10%) Frequency	120 to 240 VAC 50/60 Hz	
Power Supply DC Output Current Output	15 VDC 2.0 A	

ENVIRONMENTAL	
Operating Temperature	5 - 40°C (41 - 104°F)
Operating Humidity	10 - 90% Non-Condensing
Storage Temperature	-40 - 70°C (-40 - 158°F)
Storage Humidity	10 - 90% Non-Condensing

INTERFACE	
DC Input	1-Pin Jack Connector
Foot Pedal	1-Pin Jack Connector
Probe Inputs:	
A-Probe-	5-Pin with Insertion Key
B-Probe-	10-Pin with Insertion Key
Printer Output	BNC Connector

DISPLAY	
Type	Color (RGB) LCD Backlit Display with Touch Screen Overlay
Resolution	640 x 480 pixels (h x v)
Dimensions	
Width	135 mm (5.25”)
Height	86 mm 3.4”

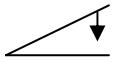
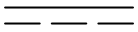
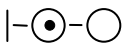
PROBES	
B-Scan Probe:	Mechanical sector scan
-Frequency	10 MHz ± 10%
-Focal Length	24 mm. ± 2mm.
A-Scan Probe:	Direct Contact
-Frequency	10MHz ± 10%
-Focal Length	25mm. ± 3mm.

PRINTER		
Model	Sony UP-890MD	
Type	Video Printer	
Paper Size		
Width	110 mm	4.3”
Roll Diameter	50 mm	2.0”

ACCESSORIES AND OPTIONS		
ITEM	B5500+	AB5500+
E-Z SCAN™ Unit	•	•
Stylus Touch Pen	•	•
Foot Pedal	•	•
AC Adapter	•	•
Instruction Manual	•	•
B-Scan Probe	•	•
A-Scan Probe	N/A	•
Coupling Gel	•	•
Printer with Paper	•	•
Calibration Cylinder	N/A	•
Carry Case	Optional	Optional
ScanViewer Software	Optional	Optional

B-SCAN SYSTEM PERFORMANCE	
Examination Modes	B-only B/a A/b
Display Scale	Electronic Markers at 2.0 mm Intervals
Measurement Accuracy Electronic Clinical	 ±0.0484 mm. ±0.1 mm.
Amplifier	Low Noise Variable Gain Nominal Gain = 100 dB

A-SCAN SYSTEM PERFORMANCE	
Examination Modes	Cataract Dense Cataract Aphakic Pseudophakic
Display Scale	Electronic Markers at 2.0mm Intervals
Measurement Accuracy Electronic Clinical	 ±0.023 mm. ±0.1 mm.
Measurement Range	18 - 40 mm.
Calibration	Automatic w/ built-in calibration cylinder.

SYMBOLS	
	Footswitch Port
	Direct Current Input
	Type BF Applied Part Output is isolated from live parts by double or reinforced insulation
	On-Charge (not currently used)-Off switch
	Attention, Consult Accompanying Documents
	Caution, Potential Hazard Exists If This Action or Function Is Not Performed Correctly
	Class II Equipment per EN60601
CE 0413	CE Mark, Complies with all applicable New Approach Directives.
	Direct Current Input Polarity
	ETL Listing Mark

ALARA SECTION AND EMISSIONS
(As Low As Reasonably Possible)

Probe Material: Lead Metanioboate

Nominal Center Frequency:

A-scan: 10 MHz

B-scan: 10 MHz

Pulse Repetition Frequency:

A-scan: 19.2 Hz

B-scan: 3800 Hz

Type: AB5500+, A-scan and B-scan.

Typical Ultrasonic Intensities in tissue listed below:*

B-SCAN

B-scan (autoscanning)

I_{SPTA}, .881 mW/cm^2

I_{SPPA} 11.45 W/cm^2

MI 0.151

Ultrasonic Power 0.133 mW

A-SCAN

I_{SPTA}, 0.0068 mW/cm^2

I_{SPPA} 3.31 W/cm^2

MI 0. 085

Ultrasonic Power .00134 mW

*Energy emitted in bursts for A-scan. Measurement must be repeated for new burst. At measured transducer focus (1.7 cm from probe tip for A-scan, 1.5 cm for B-scan). Focal point adjusted for attenuation of tissue. The output power is not adjustable. Thus, these values are also the global maxima.

The energy will always be attenuated by the tissue between the transducer and the focus when used as recommended. The values presented here are the values at the focal point, the point of maximum intensity.

It is not possible to vary the output energy of the transducer. However, to minimize exposure, measurements should be kept as short as possible during use.

If more accuracy is desired, the intensity in the body at any transducer point may be calculated according to the formula recommended by the FDA:

$$I_t = I_w \exp(-0.069fz),$$

where I_t = is the estimated in situ intensity, I_w is the measured intensity in water at the focus of the transducer (indicated in the above chart), f is the ultrasonic frequency in megahertz, and z is the distance from the face of the probe to the transducer focus in centimeters, which is the point of measurement. For this device, f = xx and z = yy. This formula was also used to calculate the derated values shown above.

Transducer parameters show considerable variation from transducer to transducer. The measured and calculated values shown above were those for an actual transducer, whose values deviated slightly from the values in the specification above, and whose values are likely to be different from the transducer with your system. However, the values in the specification should give results that are accurate enough for any practical purpose, since the intensities are very low.

There is no control for adjusting the output energy. Thus, the transducer should be applied to the eye for as short a period as possible. Remove the transducer from the eye when not making measurements. One should always minimize exposure by limiting the ultrasonic transmission to as short periods as possible.

Velocity of sound used by system (values for different eyes) are tabulated in Appendix A of this manual.

Global Maxima

The values given above are the global maxima.

Accuracy

The A-scan system measurements have an accuracy of 0.1 mm. The B-scan accuracy is 0.1 mm. These are the values that have been found in clinical practice. The corresponding theoretical values are 0.484 mm (B-scan) and 0.023 mm (A-scan). These theoretical values do not include errors caused by operator technique or uncertainty in the velocity of sound. The A-scan accuracy can be expected over a range of 18 to 40 mm of axial length. The B-scan accuracy at an acquisition of 256 rays is valid to

a depth of 50 mm; at an acquisition of 128 rays, the depth is 60 mm. Minimum is 18 mm.

Acoustic Output Reporting Tables

Typical measured results are below. There is a considerable variation in transducers, and any individual transducer may be quite different.

Table 6-1
A-Scan Acoustic Output Table

			MI	$I_{SPTA.3}$ [mW/cm^2]	$I_{SPPA.3}$ [W/cm^2]
Acoustic Output – Global Maximum Value			0.085	0.0068	3.31
Associated Acoustic Parameters	$P_{r.3}$	[MPa]	0.300		
	W_0	[mW]		0.00134	0.00134
	f_c	[MHz]	12.29	12.29	12.29
	z_{sp}	[cm]	1.7	1.7	1.7
	Beam Dimension – x_{-6}	[cm]		0.383	0.383
	Beam Dimension – y_{-6}	[cm]		0.310	0.310
	PD	[μs]	0.107		0.107
	PRF	[Hz]	19.2		19.2
	EBD Az.	[cm]		0.47	
	EBD Ele.	[cm]		0.47	

Table 6-2
B-Scan Acoustic Output Table

			MI	$I_{SPTA.3}$ [mW/cm^2]	$I_{SPPA.3}$ [W/cm^2]
Acoustic Output – Global Maximum Value			0.154	0.881	11.45
Associated Acoustic Parameters	$P_{r.3}$	[MPa]	0.475		
	W_0	[mW]		0.133	0.133
	f_c	[MHz]	9.47	9.47	9.47
	z_{sp}	[cm]	1.5		1.5
	Beam Dimension – x_{-6}	[cm]			0.088
	Beam Dimension – y_{-6}	[cm]			0.090
	PD	[μs]	0.135		0.135
	PRF	[Hz]	3800		3800
	EBD Az.	[cm]		0.60	
	EBD Ele.	[cm]		0.60	

Appendix A
VELOCITY TABLES

DEFAULT INDIVIDUAL VELOCITIES	
Classification of Eye	Velocity [m/s]
Anterior Chamber Depth (ACD)	1532
Crystalline Lens	1640
Vitreous Length	1532

REFERENCE VELOCITIES FOR SPECIFIC STRUCTURES	
Structure	Velocity [m/s]
Cornea	1641
Anterior Chamber Depth (ACD)	1532
Crystalline Lens	1640
Vitreous Length	1532
PMMA IOL	2718
Acrylic IOL	2120
Silicone-I IOL	1049
Silicone-II IOL	980

IOL CORRECTION VALUES	
IOL Material	Correction [mm]
PMMA IOL	+0.4
Acrylic IOL	+0.2
Silicone-I IOL (Velocity=1049m/s)	-0.8
Silicone-II IOL (Velocity=980m/s)	-0.4

Notes:

1. The Sonomed EZ-SCAN™ uses 2, 3, or 4 gates to measure an eye based on the "Eye Type" selected. Individual velocities are used for each area as shown in the table above. The user can enter any desired velocity to replace the default value, but this is not recommended except in the case where silicone oil or some other material is present.

2. If the velocity is changed by the user for a particular eye type, it is imperative that this velocity be reviewed and/or changed by the user before proceeding with further measurements of other eye types.

3. Manual Mode permits the user to select both the number of gates to be used as well as the individual velocities for each structure.

   Example:
   Aphakic Eye: Use two (2) gates and a velocity of 1532m/s.

4. For Pseudophakic Modes, the EZ-SCAN™ calculates the measurement using a velocity of 1532m/s (for the Anterior Chamber and Vitreous lengths), and uses a correction factor for the particular IOL material as shown in the table to the left.

   The user can enter up to 5 custom lenses with correction factors from -2.0 to +2.0.

A-Constant	S-Factor	ACD	A-Constant	S-Factor	ACD	A-Constant	S-Factor	ACD	A-Constant	S-Factor	ACD
110.0	-3.31	0.30	112.5	-1.89	1.76	115.0	-0.48	3.21	117.5	0.94	4.67
110.1	-3.25	0.36	112.6	-1.84	1.81	115.1	-0.42	3.27	117.6	1.00	4.73
110.2	-3.19	0.41	112.7	-1.78	1.87	115.2	-0.36	3.33	117.7	1.05	4.79
110.3	-3.14	0.47	112.8	-1.72	1.93	115.3	-0.31	3.39	117.8	1.11	4.85
110.4	-3.08	0.53	112.9	-1.66	1.99	115.4	-0.25	3.45	117.9	1.17	4.91
110.5	-3.02	0.59	113.0	-1.61	2.05	115.5	-0.19	3.51	118.0	1.22	4.96
110.6	-2.97	0.65	113.1	-1.55	2.11	115.6	-0.14	3.56	118.1	1.28	5.02
110.7	-2.91	0.70	113.2	-1.50	2.16	115.7	-.0.08	3.62	118.2	1.34	5.08
110.8	-2.85	0.76	113.3	-1.44	2.22	115.8	-0.02	3.68	118.3	1.39	5.14
110.9	-2.80	0.82	113.4	-1.38	2.28	115.9	0.03	3.74	118.4	1.45	5.20
111.0	-2.74	0.88	113.5	-1.32	2.34	116.0	0.09	3.80	118.5	1.51	5.26
111.1	-2.68	0.94	113.6	-1.27	2.40	116.1	0.15	3.86	118.6	1.56	5.32
111.2	-2.63	1.00	113.7	-1.21	2.46	116.2	0.20	3.91	118.7	1.62	5.37
111.3	-2.57	1.06	113.8	-1.16	2.51	116.3	0.26	3.97	118.8	1.68	5.43
111.4	-2.51	1.11	113.9	-1.10	2.57	116.4	0.32	4.03	118.9	1.73	5.49
111.5	-2.46	1.17	114.0	-1.04	2.63	116.5	0.37	4.09	119.0	1.79	5.55
111.6	-2.40	1.23	114.1	-0.98	2.69	116.6	0.43	4.15	119.1	1.85	5.61
111.7	-2.34	1.29	114.2	-0.93	2.75	116.7	0.49	4.21	119.2	1.90	5.66
111.8	-2.29	1.35	114.3	-0.87	2.81	116.8	0.54	4.26	119.3	1.96	5.72
111.9	-2.23	1.40	114.4	-0.82	2.86	116.9	0.60	4.32	119.4	2.02	5.78
112.0	-2.17	1.46	114.5	-0.76	2.92	117.0	0.66	4.38	119.5	2.07	5.84
112.1	-2.12	1.52	114.6	-0.70	2.98	117.1	0.71	4.44	119.6	2.13	5.90
112.2	-2.06	1.58	114.7	-0.64	3.04	117.2	0.77	4.50	119.7	2.19	5.96
112.3	-2.00	1.64	114.8	-0.59	3.10	117.3	0.83	4.56	119.8	2.24	6.02
112.4	-1.95	1.70	114.9	-0.53	3.16	117.4	0.88	4.62	119.9	2.30	6.07
									120.0	2.36	6.13

Information supplied by Jack T. Holladay, MD

SONOMED INC.

Appendix C
HAIGIS FORMULA

The Haigis IOL formula developed by Wolfgang Haigis, Ph.D. may be ordered as an option on the PACSCAN™ 300 and E/Z-Scan™ 5500+ systems. For a clinical reference regarding the Haigis IOL formula consult "Comparison of immersion ultrasound biometry and partial coherence interferometry for IOL calculation according to Haigis"; Haigis, W, Lege, B, Miller, N and Schneider, B; Graefes Arch Clin Exp Ophthalmol (2000) 238:765-773. Another source for information regarding the Haigis IOL formula can be found on the Internet at http://www.doctor-hill.com/haigis.htm. This website was created by Warren E. Hill, M.D.

Two different types of IOL constants referred to as the "Standard" or "Optimized" constants (a0, a1 and a2) are used when employing the Haigis IOL formula. The Optimized constants are derived based upon an analysis of at least 50 sets of postoperative patient data. To obtain the Optimized constants contact:

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At the present time there are two websites on the Internet which contain additional information and Microsoft Excel spreadsheets which can be used to record patient data for submission to derive the Optimized Haigis IOL Constants. These websites should be consulted for further information regarding the submission of clinical data.

For physicians primarily in Europe, Africa and Asia, consult the website:

http://www.augenklinik.uni-wuerzburg.de/uslab/refbfrme.htm

For physicians primarily in North and South America, consult the website:

http://www.doctor-hill.com/download.htm